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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,683	03/20/2000	MICHAEL ANTHONY CAWTHORNE	00537/163002	7045

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EXAMINER
MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
1653	14

DATE MAILED: 12/17/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/423,683	Applicant(s) CAWTHORNE ET AL.	
	Examiner Abdel A. Mohamed	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

CPA STATUS ACCEPTABLE

1. The request filed on 9/28/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/423,683 is acceptable and a CPA has been established. An action on the CPA follows.

ACKNOWLEDGMENT OF PRIORITY, PRELIMINARY AMENDMENT, IDS, RESPONSE TO SEQUENCE REQUIREMENT, STATUS OF THE APPLICATION AND CLAIMS

2. This application is filed under 35 U.S.C. 371 on 3/20/00 having a filing date of 5/13/98 of PCT/EP98/02998, which is a Continuation of U.S. Patent Application No. 08/855,311, with a filing date 5/13/97, now abandoned. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The preliminary amendment, Information Disclosure Statement (IS) and Form PTO-1449 filed 3/20/00 and the response to sequence requirement filed 1/5/01, respectively are acknowledged, entered and considered. In view of Applicant's request claim 31 has been canceled. Thus, claims 1-30 are now pending in the application. With respect to the requirements of sequence listing, Applicant's argument is persuasive. In accordance with 37 C.F.R. § 1.822(b), the sequence disclosures on page 12 and also in the claims of the instant application contain one or more D-amino acid and therefore excluded fro submitting sequence listing.

3. **OBJECTION TO THE DISCLOSURE**

The disclosure is objected to because of the following informalities: On page 5, line 9, in the recitation "(e.g., between 5 :g/day and 5 mg/day)" and on page 17, line 12 "light/dark cycles at 20 " 21C". Also, on page 12, the lines to form the structures are not clearly visible. Appropriate correction is required.

ABSTRACT MISSING

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

CLAIM OBJECTION-IMPROPER MULTIPLE DEPENDENT CLAIM

5. Claims 28 and 30 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). However, the claims have been treated on the merits.

STATEMENT OF STATUTORY BASIS, 35 U.S.C. 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 29-30 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 8-9, 12-14, 17-19, 22-26 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "somatostatin type-5 receptor selective agonist" in line 2. There is insufficient antecedent basis for this limitation in claim 2 or claim 4.

Claim 6 recites the limitation "of lowering the amount of triacylglycerols....." in lines 2-3. There is insufficient antecedent basis for this limitation in claim 1 or claim 6.

Claims 23-26 are indefinite and confusing in the recitation "Tyr(I)" because the expression is not defined in the specification nor in the claim. Appropriate clarification is required.

Claims 29-30 provide for the use of the somatostatin type-5 receptor selective agonist product in the formulation of a pharmaceutical composition for treating hyperlipidemia in a human or mammalian animal, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

CLAIMS REJECTION-35 U.S.C. § 102(b)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-8, 10, 13-15, 18, 20 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Moller et al. (Clin. Science, Vol 75, pp. 345-350, 1988).

Moller et al. disclose the use of mixed SSTR-2/SSTR-5 agonist (e.g., SMS 201-995 or somatostatin-14) for the treatment of hyperlipidemia in which the reference clearly demonstrates the lowering of triglyceride levels (See e.g., page 348, Fig. 5) and blood glycerol levels (See e.g., Fig. 4). Thus, the reference clearly anticipates the method of treating hyperlipidemia by administering a therapeutically effective amount of a type-5 selective somatostatin agonist (SSTR-5 agonist) to a patient to reduce triglyceride and glycerol levels in the blood of said patient and to a pharmaceutical formulations thereof as claimed in claims 1,3, 6-8, 10, 13-15, 18, 20 and 27-29.

CLAIMS REJECTION-35 U.S.C. § 103(a)

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moller et al. (Clin. Science, Vol 75, pp. 345-350, 1988) in view of WO 96/35950 or Degrado (attachment).

The reference of Moller et al as discussed above under the rejection 102(b) discloses the use of mixed SSTR-2/SSTR-5 agonist (e.g., SMS 201-995 or somatostatin-14) for the treatment of hyperlipidemia. The primary reference differs from claims 1-30 in not teaching the use of highly selective SSTR-5 agonists (e.g., ratio SSTR-2/SSTR-5>2) and the modification of the peptide to include D-Phe and D-Trp. However, the reference of WO 96/35950 on page 17 Table II, discloses that the compound has a K of 7.0 nM for SSTR-5 receptor (ratio SSTR-2/SSTR-5 =

0.07). Thus, the prior art discloses several somatostatin analogues with the ratios as shown on Table II), hence, it appears to be obvious to one of ordinary skill in the art to test whether these or related compounds have any pharmaceutical effect on blood lipid levels.

Further, WO 96/35950 discloses Applicant's method using Applicant's claimed peptide Phe-Phe-Phe-Trp-Lys-Thr-Phe-Thr-NH_2, However, the reference does not teach modification of peptide to include D-Phe and D-Trp; but, this known modification of the peptide of WO 96/35590 would have been obvious to one of ordinary skill in the art because Degrado discloses that introduction of D-amino acids into a peptide is "a popular modification" that results in analogs with enhanced stabilities to enzymatic degradation. Thus, the combined teachings of the prior art makes obvious the claimed invention, absent of sufficient objective factual evidence e or unexpected results to the contrary.

ACTION FINAL, FIRST ACTION

10. This is a CPA of applicant's earlier Application No. 09/272,500. All claims are drawn to the same invention claimed in the earlier parent application prior to the filing of this CPA under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.153(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Christopher S. Low

CHRISTOPHER S. F. LOW
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AAM Mohamed/AAM

December 14, 2001